Diagnosing pulmonary embolism in the context of common alternative diagnoses in primary care

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20006

Source
Nationaal Trial Register

Brief title
PECAN

Health condition

Pulmonary embolism, clinical decision rule, YEARS strategy, primary care / Longembolie, beslisregel, YEARS strategie, eerstelijnszorg

Sponsors and support

Primary sponsor: Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht (UMCU)
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The primary outcomes of this study will be both the safety and efficiency of the YEARS-

strategy in primary care.

Secondary outcome

The secondary outcomes are the alternative diagnoses besides PE and the predictors for assessing PE as most likely diagnosis by GPs.

Study description

Background summary

Rationale: Clinical decision rules and D-dimer testing are available for general practitioners to distinguish pulmonary embolism (PE) from common alternative cardiopulmonary diagnoses in patients with a suspicion of PE. However, D-dimer testing is often falsely elevated, leading to unneeded, costly and potential harmful referrals for CT pulmonary angiography (CTPA). To alleviate this problem, a risk-tailored diagnostic approach was recently tested and validated with good results in secondary care: the YEARS-strategy. In secondary care, this algorithm leads to an absolute reduction of 14% of CTPAs with a completely similar safety (only 0.4% missed PE cases), as compared to a fixed D-dimer threshold of 500 mcg/L. This strategy however is not yet implemented in primary care, and awaits validation in this healthcare setting.

Objective: Our primary objective is to prospectively implement and validate the YEARS strategy in primary care. Secondary objectives are, (i) to quantify the added diagnostic value of C-reactive protein (CRP) to a clinical assessment and D-dimer testing in order to enhance distinguishing PE from a pneumonia, (ii) to develop a polytomous logistic model for estimating the diagnostic probability of both PE and pneumonia, and (iii) to statistically quantify predictors for assessing PE as most likely diagnosis by GPs.

Study design: prospective diagnostic cohort study.

Study population: this study will include 750 patients with subacute new onset or worsening of existing shortness of breath with or without chest symptoms, which makes them suspected of having PE.

Intervention: participants will be managed by their GP according to the YEARS-strategy. Furthermore, additional blood will be drawn for CRP. There will be a clinical follow-up in primary care for 3 months in all patients to establish the final diagnosis.

Study objective

The primary hypothesis is that a novel clinical decision rule for pulmonary embolism (the YEARS strategy) is at least as safe as previous studies, yet with an increased proportion of patients safely not referred for CTPA, thus fewer false-positive D-dimer tests

Study design

There will be a clinical follow-up in primary care for 3 months in all patients to establish the final diagnosis.

Intervention

The intervention is a novel clinical decision rule for patients with a suspected pulmonary embolism: the YEARS-strategy. In this strategy, the physician scores three clinical items: (i) haemoptysis, (ii) clinical signs suggestive of deep venous thrombosis, and (iii) PE considered the most likely diagnosis. If none of these items is present, a D-dimer threshold of 1000 mcg/L is applied, while if one or more items are present, the classical threshold of 500 mcg/L is used. If a suspected patient has a D-dimer below either threshold, PE is safely ruled out. Furthermore, additional blood will be drawn for CRP in order to quantify the added diagnostic value of CRP in the diagnostic management of PE.

Contacts

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Eligibility criteria

Inclusion criteria

- Clinical suspicion of pulmonary embolism (PE), with complaints such as subacute new onset or worsening of existing shortness of breath or chest symptoms;

- Aged 18 years or older

Exclusion criteria

- Pregnant;

- Already using anticoagulants (i.e. a vitamin K antagonist, low-molecular weight heparine or a direct oral anticoagulant);

- Life expectancy < 1 month

- Haemodynamic instability

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2018
Enrollment:	750
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-08-2018

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52757
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7232
NTR-old	NTR7431
CCMO	NL64357.041.18
OMON	NL-OMON52757

Study results